(8)

No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

—v.—

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., and RITE AID CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

SUPPLEMENTAL BRIEF FOR THE PETITIONER

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The Solicitor General agrees with Petitioner that it is "erroneous" (U.S. Br. 12) to apply the *per se* rule to patent settlements in which the patentee pays the alleged infringer to exit the market and that whether to ban such settlements is an "important" issue (*see id.* 7). Yet he recommends against certiorari based on his supposedly "better reading" of the Sixth Circuit opinion that, even if right, would only slightly limit the glaring conflict with the Eleventh Circuit decision (*id.* 12-13). No fair reading of the Sixth Circuit opinion supports his view, which is the Solicitor General's alone. The Federal Trade Commission (FTC), each of the five supporting amici, every major intellectual property association in the Nation, every court to have addressed it (including Judge Posner), each of the many commentators to speak to it, and Respondents themselves all acknowledge the circuit split. *Infra* pp. 3-4. The Solicitor General's singular and strained supposition can be explained only by the government's stake in this matter, which, as this Court has recognized, deprives the Solicitor General's views of persuasive weight. *Infra* pp. 7-8. The Court should grant the Petition and consider summarily reversing the Sixth Circuit's "erroneous" application of the *per se* rule. *Infra* p. 10.

1. Setting aside the Solicitor General's bizarre reading of the Sixth Circuit decision (addressed *infra* pp. 4-7), his brief plainly supports the urgent need for the Court to grant the Petition. The Solicitor General agrees that exit or "reverse" payments are not *per se* unlawful (U.S. Br. 7-11); states that a contrary conclusion would violate "well-established principle[s]" (*id.* 7); and agrees that the Sixth Circuit decision is "erroneous" to the extent it "deem[s] illegal per se every settlement agreement that includes a reverse payment" (*id.* 12). He also agrees that the Eleventh Circuit "rejected" the view that such settlements are *per se* illegal. *Id.* 11.

2. Nor does the Solicitor General dispute that, no matter how the Sixth Circuit opinion ***should*** be read, there is surely a "perceived conflict" among the circuits, which is sufficient

to grant the Petition, *Darby v. Cisneros*, 509 U.S. 137, 142-43 (1993), given the obvious "tension" in the circuits, *Baral v. United States*, 528 U.S. 431, 434 (2000).

The Solicitor General nowhere questions AIPLA's position that its 15,000 members reasonably perceive *Cardizem* as "call[ing] into question the legality of commonly accepted provisions in patent settlement and license agreements" thus endangering "**all** patent settlements and license agreements in **all** industries" nationwide. *See* AIPLA Br. 1.[1] Nor can he, given the uniformity of disinterested views acknowledging the profound importance of the split – views that continue to be expressed. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements & the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1067 (2004) ("[m]any, maybe most, patent settlements include reverse payments. . . . If reverse payments are to be condemned without more, we may have no patent settlements at all").

Indeed, Judge Kenneth W. Starr, in a recent amicus brief penned for the generic pharmaceutical industry's challenge to the FTC's more forgiving *Schering* standard, warns of "staggering consequences" from the new "anti-settlement approach" (endorsed in *Cardizem*) that "expose[s] to potential antitrust liability not just every Hatch-Waxman settlement involving money, but virtually ***every*** settlement in patent, antitrust, or intellectual property cases." Amicus Br. of Generic Pharm. Ass'n at 21, *Schering-Plough v. FTC* (11th Cir. Jun. 8, 2004) (04-10688-AA) (original emphasis). The Solicitor General takes no issue with the reality that both innovators and patent challengers are being chilled given the "implicit exchange of money during the settlement of every patent lawsuit." *Id.* 4, 7, 21; *see* Pet. Rep. 4 (consideration exchanged in licenses and damage releases). Nor does he dispute that nationwide jurisdiction and multidistrict proceedings magnify this effect. Pet. 18-19; Pet. Rep. 3.

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[1] All emphases in this brief are added unless otherwise indicated.

3. The Solicitor General is alone in refusing to acknowledge the circuit split. The Eleventh Circuit politely "recognize[d] that the Sixth Circuit appeared to take the opposite view" but clearly concluded "we respectfully disagree." Pet. App. 145a, 146a n.26. The FTC also could not have been clearer: while "[*Cardizem*] found that it was *per se* illegal for a pioneer drug company to pay money to a generic manufacturer in return for a commitment to delay entry," "[t]he even more recent decision[] in *Valley Drug* . . . **expressly considered contrary authority and declined to apply the *per se* label**." *In re Schering-Plough Corp.*, No. 9297, Comm'n Op. 12-13 (FTC Dec. 18, 2003), appeal docketed *sub nom. Schering-Plough Corp. v. FTC*, No. 04-10688-AA (11th Cir. Feb. 13, 2004) ("*Schering*"); *see also FTC Official Says Some Effects of Recent Patent Law Reform Could Be Anticompetitive*, 2 Pharm. L. & Indust. Rep. 118 (Jan. 30, 2004) ("'This is one issue the Supreme Court's going to have the last word on,' [**FTC official** Michael S.] Wroblewski said, **noting that there is a split in the circuits** . . . with the Sixth Circuit applying a *per se* approach . . . and the Eleventh Circuit applying a rule of reason") (expressing personal views at conference); Michael B. Kades, "How FTC Policy & Practice Affects Decision Making," *Conference on Latest Thinking on Attacking/Defending Patents in the U.S. Pharmaceutical Market* (October 1, 2003) (**FTC official states** his view that *Cardizem* and *Valley Drug* "**Courts Have Split** Over" whether exit payments are *per se* illegal).

AIPLA and the other supporting amici also recognize the split, *see* AIPLA Br. 1-2 ("The Sixth Circuit's *per se* holding **conflicts directly** with [*Valley Drug* and *Schering*]" and Federal Circuit misuse case law), as does the American Bar Association, *see Antitrust & Intellectual Property*, vol. 5, no. 1 at 4 (Spring 2004) (ABA's Antitrust Section Intellectual Property Committee newsletter: *Valley Drug* "decision **sets up a direct conflict** with the Sixth Circuit"), and the New

York intellectual property bar. NYIPLA Br. 4-5 ("**stark conflict**" between *Cardizem* and *Valley Drug*).

Even the scholars cited by the Solicitor General (U.S. Br. 10 n.4, 14, 16) contradict his position and recognize the split. *See* Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, *Balancing Ease & Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 712 n.3 (2004) (describing Sixth Circuit opinion as "finding exclusion payments in pharmaceutical patent settlements illegal per se," in direct conflict with Eleventh Circuit's "rejecti[on of] per se illegality"). These authorities acknowledge that "the legality of reverse payments **remains very much a live, and hotly contested issue**" and that "two federal courts of appeals have now offered **diametrically opposing views** of these settlements." Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments*, 71 Antitrust L.J. 1069, 1069-70 (2004).

Finally, Respondents here (Pet. 9), as well as the *Valley Drug* petitioners (*see* Petition at 1, *Valley Drug Co. v. Geneva Pharm., Inc.* (03-1175)) and counsel for respondents (*see* Robert A. Milne & Michael J. Gallagher, *Recent Activity on the Brand-Generic Patent Settlement Front*, 18 Antitrust 83, 83 (Spring 2004)) acknowledge the "important" split.

4. The Sixth Circuit's language does not support the Solicitor General's peculiar view. He asks this Court to ignore the "broad language in the Sixth Circuit's opinion" (U.S. Br. 12), explicitly condemning the Stipulation's restraint on Andrx's original product, because the Sixth Circuit *also* cites certain pages of the district court opinion and another district court opinion that reference, among other things, the Stipulation's supposed restraint of "non-infringing" products and conduct (*id.* 14-15). The government says the true holding of the Sixth Circuit decision is this stray hair on the tip of the tail, and not the dog. This analysis fails.

To begin, even if the Sixth Circuit's ruling had been limited in the way the Solicitor General imagines, it would

still manifest a circuit split on a significant issue. As the Eleventh Circuit recognized, every settlement agreement reaches products that have not yet been finally adjudged to be either infringing or non-infringing. The Solicitor General's suggestion that the Sixth Circuit's ruling is limited to agreements that "reach[] non-infringing products" (U.S. Br. 13) would therefore require conducting the very litigation that the settlement was designed to avoid – and hence the circuit split.

Moreover, whatever else they did, the district court and Sixth Circuit condemned what they saw as the core restraint involving Andrx's infringing original product, not (and certainly not only) any claimed inconsequential additional restraints. Respondents alleged that, but for the Stipulation, Andrx would have launched its **original** generic product in June 1998 upon FDA approval. Pet App. 10a-11a. The district court knew that those "complaints do **not** assert antitrust claims for damages based on the theories that the [Stipulation] caused Andrx to (1) delay the sale of its June 1999 FDA approved reformulated generic product, and (2) forego relinquishing its right to the 180-day exclusivity period." *In re Cardizem CD Antitrust Litig.*, 99 MDL 1278, Order No. 80, slip. op. 50 n.11 (E.D. Mich. Nov. 13, 2003). It therefore cannot be that the *per se* holding in this damages case pertained to a violation as to which no damage is alleged. *See* Pet. App. 31a-33a. As the district court held, "the Sixth Circuit . . . necessarily rejected Andrx's arguments that only competition proven to be non-infringing is worthy of protection under the antitrust laws." Order No. 80 at 29.

The Sixth Circuit clearly stated what it was affirming: "The district court concluded that the Agreement, specifically the fact that HMR paid Andrx $10 million per quarter not to enter the market with **its generic version** of Cardizem CD, was a naked, horizontal restraint of trade and, as such, *per se* illegal." Pet. App. 13a-14a. The "generic version" both courts referred to was Andrx's original, allegedly infringing product approved by the FDA in July 1998. Pet. App. 19a

n.14 (district court addressed original, not reformulated product); *see id.* 7a (HMR alleged that "generic version of Cardizem CD that Andrx proposed would infringe"), 9a ("Andrx did not bring its generic product to market" upon July 1998 FDA approval). In its antitrust injury discussion, the Sixth Circuit described its *per se* holding as limited to the allegedly infringing "FDA-approved" product (Pet. App. 31a-32a), not some non-infringing alternative. Indeed, in setting out the "dispositive" facts supporting its finding of *per se* illegality, it never once referred to any potentially or actually non-infringing product. Pet. App. 17a-18a. It understood that Respondents were merely claiming that "from July 1998 through June 1999, Andrx kept its generic product off the market," "even after it had obtained FDA approval" for its allegedly infringing product. *Id.*

Were the Sixth Circuit's decision "hardly novel" (U.S. Br. 14), the FTC would not have explicitly criticized it for failing to take "adequate account of Supreme Court decisions that mandate a more nuanced approach." *Schering* at 13 n.26. Judge Posner's criticisms of the Sixth Circuit, *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003), only make sense if Judge Posner understood, as everyone else has, that the Sixth Circuit condemned as *per se* illegal an agreement involving an allegedly **infringing** product. Indeed, the widespread outcry regarding the Circuit's failure to account for the patentee's right to exclude cannot be squared with a construction of *Cardizem* that limits it to admittedly non-infringing products. *See* Stephen A. Stack, Jr., *Afterword: Some Further Observations on the "Pharmaceutical Wars,"* 71 Antitrust L.J. 705, 713 (2003) ("These two cases represent a binary approach; the patent is given no exclusionary effect in *Cardizem* and full exclusionary effect in *Hytrin.*").

Most significantly, the Solicitor General's tortured reading is of no practical significance. No responsible counsel aware of the Sixth Circuit's opinion would advise a client subject to suit in that circuit to settle a patent case with

a "reverse payment." As the amici amply demonstrate, it is that chill that is so profoundly affecting agreements at the heart of the new economy. *See* Pet. Rep. 3-4.[2]

5. This is not the Solicitor General's first effort to dissuade this Court from acting in its historical role of preventing overuse of the blunt and powerful *per se* rule that this Court adumbrated (Pet. Rep. 1; NYIPLA Br. 3). Consider the significant *per se* decisions over the past two decades. The Solicitor General opposed review in *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999), yet the Court granted review and, disagreeing with the government, ruled that a full rule of reason analysis was appropriate. And in at least two other cases, the Solicitor General recommended against review, as it does here; yet in both cases the Court granted certiorari and reversed the lower court's expanded application of the *per se* rule. *See* Brief for U.S. & FTC as Amici Curiae, *NYNEX Corp. v. Discon, Inc.* 525 U.S. 128 (1998) (No. 96-1570); Petitioner's Supp. Brief & Response to Brief for U.S. as Amicus Curiae, *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284 (1985) (No. 83-1368). This Court also granted review in a fourth case to ensure immediate uniformity by limiting the application of the *per se* rule, even though the Solicitor General's amicus brief opposed review, arguing that the lower courts would in time get it right. *See* Brief for U.S. as Amicus Curiae, *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717 (1988) (Nos. 85-1910/2094).

Deference is even less appropriate where the Solicitor General is not a disinterested observer. The FTC is a litigant before the Eleventh Circuit in *Schering*, which may well be affected by a decision from this Court, and evidently is

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[2] The government's strained factual distinction between *Cardizem* and *Valley Drug* – that one challenged both infringement and validity while the other only validity (*see* U.S. Br. 11) – fares no better. In both cases, defendants denied that they infringed a valid patent. Pet. App. 6a-7a, 123a. The distinction is so immaterial that even Respondents concede that both cases present "**identical facts**." *See* Pet. 9.

seeking to preserve time on this Court's docket for its own litigation. As the Nation's leading antitrust enforcer, the government tends to discount the significance of over-enforcement, including the deterrent effect that the Sixth Circuit decision is having right now on pro-competitive settlements. While the government now acknowledges that so-called "reverse payment" settlements should not be unlawful *per se*, the FTC has "vigorously enforced" the law to discourage such settlements.[3] As the Solicitor General emphasizes, the FTC was Andrx's adversary in a challenge to the very settlement at issue here. U.S. Br. 4, 13.

6. The Solicitor General asserts that because the Sixth and Eleventh Circuits both addressed interim settlements, this Court's review "would not necessarily offer guidance" for "final patent infringement settlements." U.S. Br. 17-18. But resolving the circuit split on interim settlements is itself important. In any event, a settlement's interim nature is irrelevant to the issue presented in this case, *i.e.*, whether a *per se* rule applies.

The guidance to be offered here is that patent settlements involving exit payments should be analyzed under the rule of reason. That guidance would apply to both interim and final agreements because, for purposes of the *per se* rule's inapplicability, the patent's exclusionary effect is the same. Pet. Rep. 4. Tellingly, the FTC, in its own litigation, has made no effort to draw such a distinction. Brief of FTC, *Schering-Plough Corp. v. FTC* (11th Cir. 2004) (not drawing a single interim/final distinction).

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[3] Timothy J. Muris, Statement of FTC Before Senate Judiciary Comm., S. Hrg. 108–250 at 30 (June 17, 2003) (referencing FTC's "vigorous enforcement"); William M. Sage, *Protecting Competition & Consumers: A Conversation With Timothy J. Muris*, 22 Health Affairs 101, 106 (2003) (FTC Chairman discussing enforcement aimed at brands' "attempt[s] to bribe the generics to stay out of the market"); R. Hewitt Pate, *Antitrust & Intellectual Property*, Address to AIPLA (2003) 11-12) ("FTC, in particular, has been active in the area of patent settlements").

Nothing in the Solicitor General's critique of the *per se* rule in the "reverse payment" context suggests that his conclusion turns on the settlement's interim or final nature. *See* U.S. Br. 12. When the Solicitor General summarizes the Sixth Circuit decision, he never cites language discussing the interim nature of the settlement or limiting the holding to that context. *See, e.g.*, *id.* 6; *see also id.* 5. Indeed, his "interim" discussion contains not one quote from the Sixth Circuit, *id.* 15-18, let alone one distinguishing interim from final agreements. *See also* Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments*, 87 Minn. L. Rev. 1789, 1800 (2003) (finding same antitrust concerns "[i]n either form" of settlement), *cited at* U.S. Br. 16. Nothing in the Sixth Circuit's analysis of *per se* liability turns on the interim character of the agreement.

The Solicitor General suggests various aspects of an interim settlement that might make it less pro-competitive than a comparable final settlement. *See* U.S. Br. 17. But these erroneous assertions bear only on whether interim and final settlements should be treated differently under the rule of reason, a question that would not be before this Court.

Consider the irony of the Solicitor General's suggestion that review "is unnecessary at this time" because interim settlements "appear to be rare." U.S. Br. 1, 16. One would expect interim settlements of intellectual property preliminary injunction motions to be commonplace given the prevalence of such motion practice, *see* L. Craig Metcalf, *Preliminary Injunctions & Their Availability*, 15 AIPLA Q.J. 104, 105-06 (1987), and, until the recent *per se* rulings, they were. *See* Pet. Rep. 3-4. The alleged infringer avoids such motion practice by agreeing to stay off the market in return for the patentee's promise to post a bond or pay a like amount to the alleged infringer *pendente lite*. *See* Pet. App. 145a. If the Sixth Circuit's decision is not reversed by this Court, such settlements will continue to be chilled.

7. The Solicitor General's unsupported view that recent legislation "**may**" reduce Hatch-Waxman settlements (U.S. Br. 18) is irrelevant. The Sixth Circuit explicitly invoked a "uniform" *per se* rule "applicable to all industries alike." Pet. App. 18a, 19a. Hatch-Waxman aside, the Sixth Circuit's decision eliminates all exit payments and chills settlements containing other forms of consideration flowing to alleged infringers in **all** industries. AIPLA Br. 1.

8. Given the views of the Respondents and the Solicitor General, we now wish to offer a suggestion for summary reversal. The Sixth Circuit's error is manifest, as the Solicitor General's analysis of the *per se* issue shows. Respondents are half-hearted – or less – in their defense of *per se* liability, and even claim (erroneously) that a rule of reason was applied. *See, e.g.*, Opp. 1, 6, 11-12, 14. The Solicitor General's lone view aside, there is widespread consensus that the Sixth Circuit's approach conflicts with that of the Eleventh Circuit. As the supporting amici demonstrate, as long as the Sixth Circuit decision remains law, it can only create mischief by discouraging potentially pro-competitive settlements. A reversal of the decision below, with instructions to apply the rule of reason, would eliminate that mischief, remove the conflict in the circuits, and correct an obvious error.

CONCLUSION

The petition for a writ of certiorari should be granted.

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